content as directed in the individual section.

[39 FR 18944, May 30, 1974, as amended at 40 FR 22251, Apr. 22, 1975; 40 FR 23725, June 2, 1975; 40 FR 57797, Dec. 12, 1975; 46 FR 2981, Jan. 13, 1981]

§ 436.214 Heat stability.

Store an accurately weighed portion of the sample of approximately 30 milligrams in an unstoppered 50-milliliter Erlenmeyer flask for 4 days in an electric oven at 100° C±1° C. At the end of this period, remove the flask from the oven and allow to cool in a desiccator. Accurately weigh an unheated portion of the original sample of approximately 30 milligrams. Assay both the heated and unheated samples for potency as directed in § 436.204 or § 436.205 of this chapter. Determine the percent loss from the difference in potency between the unheated original sample and the heat-treated sample.

[42 FR 59856, Nov. 22, 1977]

§ 436.215 Dissolution test.

(a) *Equipment.* Use either Apparatus 1 or 2 as described in the United States Pharmacopeia XXI dissolution test.

(b) *Procedure.* For each dosage form listed in the table in this paragraph select the appropriate dissolution medium, rotation rate, sampling time, and apparatus, and proceed as set forth in either Apparatus 1 or 2 methodology of the United States Pharmacopeia XXI dissolution test. Determine the amount of drug substance dissolved by performing the assay described in paragraph (c) of this section. The amount of dissolution medium removed for sampling purposes may be disregarded if the amount removed is not more than 15 milliliters. If more than 15 milliliters is removed, then correct for the volume removed.

Dosage form	Dissolution medium	Rotation rate [1]	Sampling time(s)	Apparatus
Amoxicillin trihydrate and clavulanate potassium chewable tablets..	900 mL distilled water	75	30 min	2
Amoxicillin trihydrate and clavulanate potassium tablets.	.....do	75	.....do	2
Azithromycin capsules.	900 mL 0.10 *M* sodium phosphate buffer, pH 6.0, 0.1 mg/mL trypsin.	100	45 min	2
Bacampicillin hydrochloride tablets.	.....do	75	.....do	2
Cefadroxil hemihydrate capsules.	900 mL distilled water	100	45 min	1
Cefadroxil hemihydrate tablets.	900 mL distilled water	50	30 min	2
Cefixime tablets	900 mL 0.05 *M* potassium phosphate buffer, pH 7.2.	100	45 min	1
Cefpodoxime proxetil tablets	900 mL pH 3.0 glycine buffer	75	30 min	2
Cefprozil tablets.	900 mL purified water	100	45 min	1
Cefuroxime axetil for oral suspension	900 mL Sorenson's Modified Phosphate Buffer, pH 7.0.	50	30 min	2
Cefuroxime axetil tablets.	900 mL 0.07*N* hydrochloric acid	55	15 min. and 45 min	2
Cephalexin hydrochloride monohydrate tablets..	900 mL distilled water	150	45 min	1
Cephradine dihydrate capsules.	900 mL 0.12*N* hydrochloric acid	75	60 min.	2
Clarithromycin tablets.	900 mL 0.10 *M* sodium acetate buffer, pH 5.0.	50	30 min.	2
Doxycycline hyclate tablets.	900 mL distilled water	75	60 min and 90 min	2
Doxycycline monohydrate hydrochloric acid capsules..	900 mL 0.1*N* hydrochloric acid.	75	60 min	2
Erythromycin particles in tablets	900 mL 0.05*M* potassium phosphate buffer, pH 6.8.	75	45 min.	2
Loracarbef capsules.	900 mL distilled water.	50	30 min	2
Oxytetracycline hydrochloride capsules..	900 mL distilled water	75	30 min and 60 min	2
Rifabutin capsules	900 mL 0.01 *N* hydrochloric acid	100	45 min	1
Tetracycline hydrochloride capsules (except 500-mg)..	.....do	75	.....do	2
Tetracycline hydrochloride capsules (500-mg)..	.....do	75	30 min, 60 min, and 90 min	2
Tetracycline hydrochloride tablets.	.....do	75	30 min and 60 min	2
Vancomycin hydrochloride capsules.	900 mL distilled water.	100	45 min	1

[1] Rotation rate of basket or paddle stirring element (revolutions per minute).